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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,580	04/15/2004	Anja Kohlrausch	01-1491	8666

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
04/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/825,580	KOHLRAUSCH, ANJA	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,9 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-5, 9, 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/2010; 3/09/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed January 14, 2010 has been received and entered into present application. No claims were added or canceled by applicant. Thus claims 1-2, 4-5, 9, 12-20 are pending.

Applicants' arguments, filed January 14, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-5, 9, and 12-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-9 of U.S. Patent No. 6,737,432 in view of Lacourciere et al. (Comparison of fixed-dose combination of 40mg telmisartan plus 12.5mg hydrochlorothiazide with 40mg telmisartan in the control of mild to moderate hypertension, already of record in the previous office action mailed July 30, 2009).

Applicant has amended the claims to specify a tablet or capsule and a specific melting point. However the tablet/capsule is taught by Lacourciere et al. and the specific melting point is taught by US 6,737,432 and thus the double patenting rejection still applies. Applicant has stated that since the scope of the claims may change and moot the rejection there is no need to address this issue at this time. This argument is

not found persuasive, because the double patenting rejection still applies and the claims are not in condition for allowance. Should claim amendments overcome the double patenting the rejection will be withdrawn however it is proper to maintain this rejection until either the double patenting rejection no longer applies or the claims are otherwise allowable and a terminal disclaimer has been filed.

THIS REJECTION IS MAINTAINED.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 9, and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacourciere et al. (Comparison of fixed-dose combination of 40mg telmisartan plus 12.5mg hydrochlorothiazide with 40mg telmisartan in the control of mild to moderate hypertension) in view of Donsbach et al. (US 2003/0130331 A1), each already of record on pages 7-10 of the previous office action dated July 30, 2009 the reasons of which are hereby incorporated by reference.

Applicant has amended the claims to specify a tablet or capsule and to specify a melting point for the crystalline telmisartan sodium salt. However, since Donsbach et al. teaches tablets (page 5, [0062]) as well as the same melting point (page 6, claim 1) those amendments are also obvious over Lacourciere et al. in view of Donsbach et al. Applicant has argued that Donsbach et al. teaches tablets of the sodium salt of telmisartan but does not mention the fixed dosage composition with the diuretic hydrochlorothiazide. This argument is not found persuasive because they do not have to teach the combination as Lacourciere et al. teaches a fixed dose combination of telmisartan and hydrochlorothiazide and Donsbach et al. is relied upon for teaching an improved form of telmisartan that would be substituted in the composition of Lacourciere et al. Applicant also argues that the dosages in Donsbach et al. are much smaller (0.25-mg-1mg) than those claimed of 40 and 80mg and that one would not have motivation to somehow arrive at those dosages. This argument is not found persuasive because Lacourciere et al. teach 40mg (see title of reference and abstract) and the disclosure of Donsbach et al. is directed towards a new and better formulation but not a method of treating and therefore one of ordinary skill in the art at the time of the invention would

look to the dosage of 40mg for telmisartan sodium that is taught in Lacourciere et al. and use that dosage as a starting point to finding the optimum dosage for that specific formulation.

Applicant's arguments have been carefully and fully considered but are not deemed persuasive and thus the rejection of claims 1-2, 4-5, 9, and 12-20 is **maintained.**

Claims 1-2, 4-5, 9, and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauel et al. (US 5,591,762) in view of Dinnebier et al. (Journal of Pharmaceutical Sciences, 2000, Vol. 89 (11), pages 1465-1479), in further view of Vippagunta et al. (Advanced Drug Delivery Reviews, 2001, vol. 48, pages 3-2), each already of record on pages 11-13 of the previous office action dated July 30, 2009 the reasons of which are hereby incorporated by reference.

Applicant has amended the claims to specify a tablet or capsule and to specify a melting point for the crystalline telmisartan sodium salt. Applicant has argued that this overcomes the rejection over Hauel et al. because the example 232 of Hauel et al. is an oral suspension. This argument is not found persuasive as Hauel et al. teaches tablets and capsules for their invention (column 57, lines 1-2) and it would have been obvious that the invention could be formulated as a capsule. Applicant also argued that Dinnebier et al. does not teach the sodium salt of telmisartan however Hauel et al. teaches pharmaceutically acceptable salt forms of their compositions (column 56, lines

35-45) and the sodium salt is the most common salt form of telmisartan and thus it would have been obvious to one of ordinary skill in the art that the crystalline form of telmisartan sodium could be substituted for the telmisartan and acceptable salts of Hauel et al.

Applicant's arguments have been carefully and fully considered but are not deemed persuasive and thus the rejection of claims 1-2, 4-5, 9, and 12-20 is **maintained.**

Conclusion

Rejection of claims 1-2, 4-5, 9, and 12-20 is deemed proper and is **maintained.**

No Claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Primary Examiner, Art Unit 1614